

House of Representatives

General Assembly

File No. 218

February Session, 2000

Substitute House Bill No. 5592

House of Representatives, March 23, 2000

The Committee on General Law reported through REP. FOX of the 144th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

An Act Concerning The Return Of Dispensed Medicines By Nursing Homes.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

- Section 1. (NEW) (a) Each long-term care facility shall return to the
- 2 vendor pharmacy, for repackaging and reimbursement, drug products
- 3 that were dispensed to a patient and not used if such drug products
- 4 are (1) prescription drug products that are not controlled substances;
- 5 (2) sealed in individually packaged units; (3) returned to the vendor
- 6 pharmacy within the recommended period of shelf life for the purpose
- 7 of redispensing such drug products; and (4) oral and parenteral
- 8 medication in single-dose sealed containers approved by the federal
- 9 Food and Drug Administration, topical or inhalant drug products in
- 10 units of use containers approved by the federal Food and Drug
- 11 Administration or parenteral medications in multiple-dose sealed
- 12 containers approved by the federal Food and Drug Administration
- 13 from which no doses have been withdrawn.

14 (b) Notwithstanding the provisions of subsection (a) of this section:

- 15 (1) If such drug products are packaged in manufacturer's unit-dose 16 packages, such drug products shall be returned for redispensing if 17 such drugs can be redispensed for use before the expiration date, if 18 any, indicated on the package.
 - (2) If such drug products are repackaged in manufacturer's unitdose or multiple-dose blister packs, such drug products shall be returned for redispensing if (A) the date on which such drug product was repackaged, such drug product's lot number and such drug product's expiration date are indicated clearly on the package of such repackaged drug; (B) ninety days or fewer have elapsed from the date of repackaging of such drug product; and (C) a repackaging log is maintained by the pharmacy in the case of drug products repackaged in advance of immediate needs.
 - (3) No drug products dispensed in a bulk dispensing container may be returned to the vendor pharmacy.
 - (c) Each long-term care facility shall establish procedures for the return of unused drug products to the vendor pharmacy from which such drug products were purchased.
 - (d) The Department of Consumer Protection shall adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to carry out the provisions of this section. Such regulations shall govern the repackaging and labeling of drug products returned pursuant to subsections (a) and (b) of this section.
 - (e) The Commissioner of Social Services shall establish the rate of reimbursement that shall be paid to the vendor pharmacies by the manufacturers of such drug products returned to such vendor pharmacies pursuant to the provisions of this section.
- 42 Sec. 2. Section 17b-363 of the general statutes is repealed.

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GL Committee Vote: Yea 15 Nay 0 JFS

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact: Potential Significant Savings, Significant Cost

Affected Agencies: Department of Social Services, Department of

Consumer Protection

Municipal Impact: None

Explanation

State Impact:

This bill may result in significant savings under the Department of Social Services' (DSS) Medicaid program if it reduces unnecessary disposal of pharmaceuticals in nursing homes. The department currently spends approximately \$70 million on drugs for the 20,000 individuals receiving long-term care under the Medicaid program. It is estimated that up to 10% of the prescription drugs delivered to nursing homes are unused. Assuming that these unused drugs can be returned to the issuing pharmacy under the terms of this bill and that DSS would establish reimbursement rates similar to the actual cost of the drugs, this bill could result in savings of up to \$7 million. The final savings will be dependent upon the reimbursement rate set by DSS and the amount of unused drugs that can be returned to the pharmacies under the terms of the bill.

In addition, requiring prescription drugs to be reused rather than destroyed would likely lead to changes in the initial dispensing of

pharmaceuticals sent to nursing homes. Any reduction in the initial distribution of unused drugs will also contribute to savings.

It is anticipated the Department of Consumer Protection will require an additional Drug Control Agent with salary and associated expenses of \$100,000, to administer the provisions of this bill.

OLR Bill Analysis

sHB 5592

AN ACT CONCERNING THE RETURN OF DISPENSED MEDICINES BY NURSING HOMES.

SUMMARY:

This bill requires long-term care facilities to return to the pharmacy, for repackaging and reimbursement, drugs that were dispensed to a patient but not used if they are:

- 1. prescription drugs but not controlled substances,
- 2. sealed in individually packaged units,
- 3. returned to the vendor pharmacy during the recommended shelf life of the product for redispensing,
- 4. in single-dose sealed containers approved by the federal Food and Drug Administration if they are oral or parenteral products,
- 5. in units-of-use FDA-approved containers if they are topical or inhalant drug products, or
- 6. in multiple-dose sealed FDA-approved containers from which no doses have been withdrawn if parenteral medications.

The bill prohibits returning drugs dispensed in a bulk dispensing container.

In addition, the bill sets conditions concerning expiration dates and requires long-term care facilities, the Department of Consumer Protection (DCP), and the social services commissioner to take steps to implement its requirements.

Finally, the bill eliminates obsolete references to a demonstration

program for returning dispensed prescription drugs.

EFFECTIVE DATE: October 1, 2000

EXPIRATION DATES

If the drugs are packaged in the manufacturer's unit-dose packages, they must be returned if they can be redispensed for use before the expiration date, if any, stated on the package. If they are repackaged in the manufacturer's unit-dose or multiple-dose blister packs, they must be returned if (1) the package clearly indicates (a) the date of repackaging, (b) the drug's lot number, and (c) the product's expiration date; (2) 90 days or fewer have elapsed since the drug was repackaged; and (3) a repackaging log is kept by the pharmacy in the case of drugs that are repackaged before needed.

IMPLEMENTATION REQUIREMENTS

The bill requires long-term care facilities to establish procedures for returning drugs to the pharmacy from which they were purchased. It requires the Department of Consumer Protection to adopt implementing regulations concerned with the repackaging and labeling of returned drugs. It requires the social services commissioner to set the reimbursement rate that must be paid to pharmacies by the manufacturers.

BACKGROUND

Demonstration Program

The law allowed the social services commissioner to establish a twoyear demonstration program to explore methods of returning and dispensing prescription drugs that have been dispensed to patients in long-term care facilities. It required the commissioner to report on the program to the Human Services and Appropriations committees by February 15, 2000. The department has not yet submitted the report.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute Yea 15 Nay 0